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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,518	12/21/2001	Carine Capiou	B45175	4370

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EXAMINER

DEVI, SARVAMANGALA J N

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 07/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

34.

Office Action Summary

Application No.

09/914,518

Applicant(s)

CAPIAU ET AL.

Examiner

S. Devi, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/06/03.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 and 16-23 ~~is/are~~ are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-14 and 16-23 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Lack of Unity

- 1) Claim 15 has been canceled via the amendment filed 09/19/01.
Claims 6, 7 and 11 have been amended via the amendment filed 09/19/01.
New claim 23 has been added via the amendment filed 09/19/01.
Claims 1-14 and 16-23 are under prosecution.
- 2) Restriction to one of the following inventions is required under PCT Rule 13.1 and 13.2:
 - I. Claims 1-8 and 23, drawn to an immunogenic composition comprising one or more of polysaccharide conjugate antigens comprising one pathogenic bacterial polysaccharide conjugated to protein D from *Haemophilus influenzae*.
 - II. Claims 9 and 10, drawn to an immunogenic composition comprising *N. meningitidis* capsular polysaccharide-tetanus toxoid conjugate, meningococcal C and Y capsular polysaccharides conjugated to protein D from *H. influenzae*.
 - III. Claim 17, drawn to a method of producing an immunogenic composition to a plurality of pathogenic bacteria.
 - IV. Claim 18, drawn to a method of treating a patient by administering an immunogenic composition of claim 1.

Claims 11-14, 16, 20, 21 and 23 are considered as linking claims and would be joined with one of inventions I and II, if elected.
- 3) Inventions I through IV lack unity of invention due to the absence of a special technical feature. The special technical feature of the first claimed product of invention I is an immunogenic composition comprising a plurality of polysaccharide conjugate antigens consisting of one pathogenic bacterial polysaccharide conjugated to protein D from *Haemophilus influenzae*. Such a product, however, was already disclosed in the art. For example, as set forth in the international search report, Snapper *et al.* (WO 96/32963, already of record) taught such an immunogenic composition. The special technical features of inventions III and IV respectively are a method of making and a method of using the product of invention. The special technical feature of invention II is an immunogenic composition comprising *H. influenzae* b capsular polysaccharide-tetanus toxoid conjugate, meningococcal C and Y capsular polysaccharides conjugated to protein D from *H. influenzae* with or without pneumococcal capsular polysaccharide conjugated to protein D from *H. influenzae*. Individually, the first claimed product of and the method of making and the first method of using the product are a permitted combination of categories under PCT Rule 13.2. However, since the special technical feature is already disclosed in the art, the special technical feature does not define over the prior art. Clearly, instant inventions lack unity. It is further noted

that, technically, the absence of a special technical feature would permit the separation of making or using the product from the product itself.

4) This application contains claim(s) directed to more than one species to be examined. The polysaccharide antigen species recited in claim 2 and the protein antigen species recited in claims 6-8 are listed below, which do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the various sequence species do not share significant structural elements:

Polysaccharide antigens: Vi polysaccharides from *Salmonella typhi*; meningococcal polysaccharides; modified polysaccharides of group B meningococcus; polysaccharides from *Staphylococcus aureus*; polysaccharides from *Streptococcus agalactiae*; polysaccharides from *Streptococcus pneumoniae*; polysaccharides from *Mycobacteria*; polysaccharide from *Cryptococcus neoformans*; lipopolysaccharides of non-typeable *Haemophilus influenzae*; capsular polysaccharide from *Haemophilus influenzae* b; lipopolysaccharides of *Moraxella catarrhalis*; lipopolysaccharides of *Shigella sonnei*; and LPPG of *Trypanosoma cruzi*.

Protein antigen species: pneumolysin toxin; PspA or variants thereof; PspC or variants thereof; PssA or variants thereof; glyceraldehydes-3-phosphate dehydrogenase; CbpA or variants thereof.

5) Applicants are required, in reply to this action, to elect a single disclosed species even though this requirement is traversed.

Should Applicants traverse on the ground that the species are not patentably distinct, Applicants should submit evidence or identify such evidence now of record, showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C § 103(a) of the other invention.

6) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989.

7) Papers related to this application may be submitted to Group 1600, AU 1645 by

Serial Number 09/914,518

Art Unit: 1645

facsimile transmission. Papers should be transmitted via the PTO Fax Center which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9307.

8) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

July, 2004


S. DEVI, PH.D.
PRIMARY EXAMINER